

REMARKS

Applicants thank the Examiner for the very thorough consideration given the present application. Claims 11, 14-15 and 20-23 are currently pending in this application. Claims 12-13 and 24-25 have been cancelled. No new matter has been added by way of the present amendment. For instance, the amendment to claim 11 is supported by previously presented claims 12, 13 and 24, now cancelled, as well as the Specification at, for example, paragraphs [0044] and [0085]. Accordingly, no new matter has been added.

In view of the amendments and remarks herein, Applicants respectfully request that the Examiner withdraw all outstanding rejections and allow the currently pending claims.

Issues Under 35 U.S.C. 102(b)

Claims 11, 13, 20-22 and 25 stand rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al. (U.S. 6,436,132) (hereinafter Patel '132). Applicants respectfully traverse.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of anticipation. For anticipation under 35 U.S.C. §102, the reference must teach each and every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present". *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Id.*

As amended, the present invention is directed, *inter alia*, to a medical instrument comprising a medical instrument substrate selected from the group consisting of a stent, a catheter and a medical tube, and a film including a resin and having a porous structure formed at least on its surface, the surface of the medical instrument substrate being entirely or partially covered with the film, wherein the porous structure of the film is a honeycomb structure, pores of the porous structure of the film have an average pore size of 0.1 to 20 μm , and the thickness of the film is 0.5 to 20 μm (see, e.g., claim 1). Patel '132 fails to explicitly or implicitly disclose a medical instrument as claimed.

The Examiner asserts that Patel '132 discloses a stent comprising a stent surface and an ePTFE covering, wherein the surface of the medical instrument is entirely or partially covered with the film. However, Applicants submit that Patel '132 does not disclose a porous honeycomb structure as presently claimed.

Moreover, Patel '132 discloses that a film having a porous structure having a small pore size is not suitable for use as a stent cover. As part of the "Background of the Invention", Patel '132 discloses a GORE-TEX Vascular Graft having an average pore size of 10 to 100 μm , used as a stent cover. Patel '132 further discloses that micro-porous materials like GORE-TEX Vascular Graft are effective at preventing diseased tissue ingrowth. However, Patel '132 explicitly acknowledges that, due to the very small pore size of the stent cover, re-endothelialization with new healthy tissue may be somewhat compromised (see col. 2, lines 19-49). Thus, the invention of Patel '132 is directed to a stent having a multiplicity of cell openings **greater than 100 microns in width** which can overcome the issues associated with the GORE-TEX Vascular Graft and similar stent covers (emphasis added).

Evidently, Patel '132 fails to teach each and every limitation of the present invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Issues Under 35 U.S.C. 103(a)

Patel '132 in view of Nishikawa

Claims 12, 14 and 23 stand rejected under 35 U.S.C. 103(a) as obvious over Patel '132 in view of Nishikawa et al. ("*Mesoscopic patterning of cell adhesive substrates as novel biofunctional interfaces*"). Additionally, claim 15 stands rejected as anticipated by Patel '132 or, in the alternative, as obvious over Patel '132 in view of Nishikawa. Applicants respectfully traverse.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ 2d 1385 (U.S. 2007). There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* The Supreme Court of the United States has recently held that the "teaching, suggestion, motivation test" is a valid test for obviousness, albeit one which cannot be too rigidly applied. *Id.* "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements;

instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

As discussed above, Patel ‘132 fails to teach a medical instrument as claimed. Nishikawa fails to cure the deficiencies of Patel ‘132. Nishikawa discloses the following:

(a) honeycomb-patterned films are prepared on cover glasses by casting of a polymer 1 or 2 solution;

(b) cell adhesion to the honeycomb films is described, from the view point of the effect of the honeycomb size;

(c) the honeycomb film of polymer 1 is measured at the inner (A) and outer (B) regions of the cast area. The average diameters obtained are: 4.6 μ m at the inner region and 2.0 μ m at the outer region;

(d) differences in cell adhesion are observed for the inner and outer regions of honeycomb films of polymer 2;

(e) aorta ECs are attached to the whole region of the honeycomb film of polymer 1; ECs are not attached to the outer region of the honeycomb film of polymer 2;

(f) further studies are necessary for the elucidation of the region between the honeycomb structure and cell adhesion (*see* Section 3.3, “Cell adhesion to the honeycomb films”).

Evidently, Nishikawa does not teach or suggest a medical instrument as claimed, and thus fails to cure the deficiencies of Patel ‘132. Furthermore, Applicants note that Nishikawa only discloses the degree of cell adhesion to the surface of the film, and fails to disclose or suggest the present invention. For this reason alone, this rejection is improper and should be withdrawn.

Moreover, Applicants submit that one skilled in the art would not have been motivated to combine the references as proposed. The porosity film which is described in Nishikawa has a smaller pore size than that of the film of Patel '132. Therefore, one skilled in the art would not have considered using the porosity film having a honeycomb structure of Nishikawa in Patel's stent cover.

Moreover, the area having a pore size smaller than $2\mu\text{m}$ in Nishikawa's film (which the Examiner refers to) is very small, because the diameter of the film is about 1 cm. Therefore, one skilled in the art would not consider using such a film as a cover for a medical instrument.

In view of the above, reconsideration and withdrawal of this rejection are respectfully requested.

Patel '132 in view of Makoto

Claim 24 stands rejected as obvious over Patel '132 in view of Makoto et al. (JP 2003-102849) (hereinafter "Makoto"). Applicants respectfully traverse.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. As discussed above, Patel '132 fails to teach a medical instrument as claimed. Makoto fails to cure the deficiencies of Patel '132.

Makoto discloses a stent indwelling in a living body having a specific structure and a cylindrical cover, wherein the cylindrical cover comprises the porosity film and a resin for formation of an adhesive layer. However, Makoto does not teach or suggest a porosity film having a honeycomb structure. Clearly, Makoto does not teach or suggest a medical instrument

as claimed, and thus fails to cure the deficiencies of Patel '132. For this reason alone, this rejection is improper and should be withdrawn.

Moreover, Applicants submit that one skilled in the art would not have been motivated to combine the references as proposed. Makoto teaches that the thickness of the porosity film is 10-200 μ m, and the pore size of the porosity film is about 0.1 - 10 μ m (see claim 1 of Makoto; see also (0022)-(0023)). Evidently, Makoto teaches that the pore size of the porosity film is very small. Applicants submit that one skilled in the art would not consider using such a small-sized film as a cover for a medical instrument such as Patel's.

In view of the above, reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

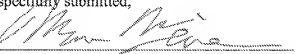
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and objections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Vanessa Perez-Ramos Reg. No. 61,158 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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